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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,092	07/10/2000	Edwin W. Ades	68430	9419

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/613,092	ADES ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *2-10 and 12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 03/15/04 in response to the non-final office Action mailed 12/11/03. With this, Applicants have amended the first paragraph of the specification.

Status of Claims

2) No claims have been amended via the amendment filed 03/15/04.

Claims 1-20 are pending.

Claims 1 and 11 are under examination.

Sequence Listing

3) Acknowledgment is made of Applicants' substitute sequence listing filed 03/2004, which has been entered.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

6) The objection to the specification made in paragraph 6 of the Office Action mailed 12/11/03 as containing new matter is withdrawn in light of Applicants' amendments to the specification.

Objection(s) Maintained

7) The objection to the specification made in paragraph 8(b) of the Office Action mailed 09/17/02 and maintained in paragraph 7 of the Office Action mailed 04/30/03 and paragraph 5 of the Office Action mailed 12/11/03, with regard to the sequence non-compliance, is maintained for reasons set forth therein. It is noted that a substitute Sequence Listing is submitted along with the amendment filed in March 2004. However, the specification, on identified pages, has not been amended to identify the amino acid sequence(s) by a SEQ ID number, as required under 37 CFR

1.821(a)(1) and (a)(2). It should be noted that 37 CFR 1.821 (a)(2)(c-d) states that each sequence disclosed must appear separately in the 'Sequence listing' **and** in the text of the description and claims. See M.P.E.P 2431. The objection stands.

Rejection(s) Maintained

8) The rejection of claim 1 made in paragraph 8 of the Office Action mailed 12/11/03 under 35 U.S.C § 103(a) as being unpatentable over Sampson *et al.* (US 6,217,884) in view of Tam (*In*: *Peptide Antigens*: *A Practical Approach.* (Ed) Wisdom G.B. IRL Press, Oxford University Press, New York, pp. 83-90. 1994 - already of record), or Huang *et al.* (*Mol. Immunol.* 31: 1191-1199, 1994 - already of record) and Harlow *et al.* (*In*: *Antibodies*: *A Laboratory Manual.* Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988), is maintained for reasons set forth therein and herebelow.

Applicants contend that Sampson *et al.* is not prior art and that it is an improper reference because it was filed on December 28, 2003. Applicants submit that the instant application has a priority date of March 02, 1998. Applicants state that Tam, Huang *et al.* or Harlow *et al.* do not alone or in combination teach or suggest all the limitations of the claims.

Applicants' arguments have been carefully considered, but are non-persuasive. Contrary to Applicants' assertion, Sampson *et al.* is properly applied as prior art since its effective filing date is at least 17 September 1996, if not 17 September 1991. The *prima facie* case of obviousness as set forth in paragraph 8 of the Office Action mailed 12/11/03, along with the establishment of a clear motivation, is maintained.

9) The rejection of claim 1 made in paragraph 9 of the Office Action mailed 12/11/03 under 35 U.S.C § 103(a) as being unpatentable over Nuijens *et al.* (WO 9117258) in view of Tam (*In*: *Peptide Antigens*: *A Practical Approach.* (Ed) Wisdom G.B. IRL Press, Oxford University Press, New York, pp. 83-90. 1994 - already of record), or Huang *et al.* (*Mol. Immunol.* 31: 1191-1199, 1994 - already of record) and Harlow *et al.* (*In*: *Antibodies*: *A Laboratory Manual.* Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988), is maintained for reasons set forth therein and herebelow.

Applicants contend that the Office has attempted to equate the disclosure of a larger Factor XII sequence in Nuijens *et al.* that includes SYQHDL as a disclosure of SEQ ID NO: 10. Applicants allege that this is equivalent of using the disclosure of the entire human genome to argue that a

specific small peptide which exists therein is obvious. Applicants further allege the Office as having argued that there is some suggestion to modify the peptide disclosed in Nuijens *et al.* to 'arrive at SEQ ID NO: 10' without stating any putative motivation to do so. Applicants state that there is no suggestion in Nuijens *et al.*, Tam or Huang *et al.* Applicants submit that the possibility that one would look to Nuijens *et al.* for the design of a *Streptococcus pneumoniae* peptide is minute. Applicants allege that the proteins are different and that there is no basis for similarity of structure or function. Applicants cite case law and MPEP 2143.01 and state that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. Applicants state that antibodies bind tertiary structures and 'removing peptides from a sequence' could effectively change the folding pattern and thus the target for the antibody. Applicants allege that there is no indication that the smaller peptide, SEQ ID NO: 10, would be suitable as a target for an antibody as proposed by Nuijens *et al.* Applicants further allege that there is no suggestion anywhere in any of the cited art that the peptides of Nuijens *et al.* could be improved by 'truncating the peptides' and then modifying the peptide to become a multiple antigen peptide. Applicants contend that a peptide that specifically binds an antibody for Factor XII and also happens to bind PsaA to some degree is not a peptide that immunospecifically binds to PsaA. Applicants acknowledge that both the instant invention and the disclosure of Nuijens *et al.* involve the same art of peptides, yet allege that Nuijens *et al.* is not analogous art. Applicants cite case law and MPEP 2145, the latter as stating that a prior art reference is analogous if the reference is in the field of the Applicant's endeavor, or, if not, the reference is reasonably pertinent to the particular problem with which the endeavor was concerned.

Applicants' arguments have been carefully considered, but are non-persuasive. Contrary to Applicants' assertion, Nuijens' peptide is not a large sequence and it does not represent the entire human genome or the entire protein. Nothing in claim 1 requires the claimed peptide to be smaller in size than Nuijens's about 12 amino acid-long peptide as disclosed at line 13 on page 14 under Example II. Claim 1 does not place any size limit on the claimed peptide. Claim 1 fails to identify the claimed peptide by its structure, i.e., SEQ ID number. Therefore, the claimed peptide does not exclude Nuijens's SYQHDL-containing peptide. Since the recited peptide or protein is not identified by one or more structural limitations, it encompasses Nuijens's synthetic peptide. Unlike claim 11,

the instant claim contains a functional limitation without reciting any structure. Via the sequence identity with a six amino acid-long peptide from the SEQ ID NO: 6 of the instant specification, the Office has established that the prior art peptide has the exact identical structure of a peptide from SEQ ID NO: 6, SYQHDL, and is long enough to serve as an antigenic determinant or epitope. The source of this structurally identical peptide is irrelevant since a chemically synthesized peptide, not isolated *per se* from *Streptococcus pneumoniae,* is also encompassed within the scope of the claim. Thus, Applicants' argument that there is no basis for similarity of structure is inaccurate. The functional limitation, on which the prior art reference is silent, is considered as an intrinsic property of the prior art peptide, or a function of the prior art peptide uncharacterized at that time. With regard to Applicants' remark on the immunospecific binding of the peptide to an anti-PsaA monoclonal antibody, it should be noted that SYQHDL does form an epitope for the PsaA-specific monoclonal antibody, 1B6, as evidenced by the teachings of Srivastava *et al.* (*Hybridoma* 19: 23-31, 2000). The SYQHDL epitope-containing peptide existed at the time of the invention as taught by Nuijens *et al.* at line 13 on page 14 under Example II. Where the only difference between the claimed product and the prior art product is recited in the functional language, i.e., by what it does rather than what it is, it is incumbent upon Applicants, when challenged by the USPTO, to demonstrate that the prior art product does not actually possess those characteristics. Applicants have not shown that the underlying structure of the prior art peptide, SYQHDL, differs from that of the instantly recited peptide. The mere structural limitation of a 'peptide' does not impart a specific structure that distinguishes the peptide of the prior art from the recited peptide. It should be noted that Nuijens *et al.* taught using the SYQHDL-containing peptide as an immunogen by conjugating to a protein carrier. There is no need for Nuijens *et al.* to provide any suggestion or motivation to modify the peptide disclosed in Nuijens *et al.* to 'arrive at SEQ ID NO: 10', because claim 1 does not include the limitation 'SEQ ID NO: 10'. Contrary to Applicants' allegation, the Office Action did not state of 'removing peptides from a sequence' or modifying the prior art peptide by 'truncating the peptides'. See the concluding paragraph of the instant rejection which is reproduced herebelow:

> Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Nuijens' PsaA peptide as a multiple antigen peptide with a built-in-adjuvant as taught by Tam, to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of presenting Nuijens' PsaA peptide as a multiple antigen peptide with a built-in-adjuvant for the purpose of advantageously

providing a very high density of the peptide mimic as taught by Tam, or for avoiding the use of a protein carrier and avoiding structural ambiguity of a conjugate as taught by Huang *et al.*

Thus, there is no basis for Applicants' allegation that the proposed modification would be unsatisfactory. The proposed modification would not render the prior art peptide being modified unsatisfactory for its intended purpose as is set forth *supra*. Furthermore, as Applicants acknowledge, the teachings of Nuijens *et al.* are in the analogous art of peptides. In addition, the teachings of Nuijens *et al.* are also in the analogous art related to epitopes, and peptide immunogens used to produce antibodies. The instant claim is related to the art of an epitope-containing peptide for use as an immunogen. Clearly, the disclosure of Nuijens *et al.* is reasonably pertinent and therefore Nuijens *et al.* is not non-analogous art. The rejection stands.

Remarks

10) Claim 1 stands rejected. Claim 11 stands objected to for being dependent from a rejected claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim.

This application contains claims drawn to non-elected inventions. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

11) **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the

notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

13) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2004

S. DEVI, PH.D.
PRIMARY EXAMINER